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10/562,243	12/22/2005	Clara Lucia Garcia-Rodenas	3712036.00694	6067
29157 K&L Gates LLP P.O. Box 1135 CHICAGO, IL 60690	7590 12/09/2010		<div>EXAMINER</div> <div>GANGLE, BRIAN J</div>	
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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chicago.patents@klgates.com

# Office Action Summary

**Application No.**

10/562,243

**Applicant(s)**

GARCIA-RODENAS ET AL.

**Examiner**

BRIAN J. GANGLE

**Art Unit**

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 12, 13, 15, 16, 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11, 17-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/06)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/19/2009 has been entered.

The amendment and remarks, filed 10/27/2009, are acknowledged. Claims 11 and 17-18 are amended. Claims 1-13 and 15-20 are pending. Claims 1-10, 12-13, 15-16, and 19-20 are withdrawn as being drawn to non-elected inventions. Claims 11 and 17-18 are currently under examination.

### ***Claim Rejections Withdrawn***

The rejection of claim 17 under 35 U.S.C. 112, second paragraph as being rendered vague and indefinite by the phrase "further comprising the step of ensuring an optimal barrier function in infants," is withdrawn in light of applicant's amendment thereto.

The rejection of claim 18 under 35 U.S.C. 112, second paragraph as being rendered vague and indefinite by the phrase "further comprising the step of reducing the risk of developing allergy and infection," is withdrawn in light of applicant's amendment thereto.

### ***Claim Rejections Maintained***

#### ***35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 11 and 17-18 under 35 U.S.C. 102(b) as being anticipated by Haschke *et al.* (WO 01/64225 A1, 2001), is maintained for the reasons set forth in the previous office action.

**Applicant argues:**

1. That applicant has surprisingly found that gut barrier function or gastrointestinal health may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. Applicant asserts that the microorganisms of the claims differ in their ability to survive in the different parts of the gastro-intestinal tract and can be incorporated into a cocktail with bioactive ingredients that reinforce their effects by stimulating the maturation of barrier mechanisms. Applicant asserts that the microorganisms of the present invention are designed to release the specific bioactive ingredients at a certain location of the gut depending on the sort of pretreatment undergone by the microorganism and that the polyamines and/or polyamine precursors of amended claim 11 also provide the advantages of substances that have the potential to favor intestinal cell differentiation.

2. That Haschke *et al.* fail to disclose or suggest administering a composition comprising at least one substance selected from the group consisting of fats, non-digestible oligosaccharides, or combinations thereof and at least one microorganism, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine. Applicant argues that, instead, Haschke is directed toward a carbohydrate formulation which include, primarily, an effective amount of a prebiotic. Applicant asserts that Haschke does not suggest the use of a polyamide or polyamide precursor, let alone those recited in claim 11.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, the claims lack any mention of particular organisms that are designed to release specific bioactive ingredients in specific locations of the gut. What is required by the claims is administration of a combination of fats or non-digestible oligosaccharides and at least one microorganism, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine. This is exactly what is taught by Haschke *et al.*

Regarding argument 2, the "carbohydrate formulation" Haschke discloses is not composed only of carbohydrates. Haschke explicitly discloses the inclusion of probiotic microorganisms and milk (see pages 3, 4, 5, and 6, for example). Bacteria such as *Bifidobacterium* contain numerous proteins, some of which include arginine. Moreover,

Haschke includes milk in their composition. It is known in the art spermine and spermidine are constituents of milk (see for example, Motyl *et al.*, Comp. Biochem. Physiol., 111B:427-433, 1995). Therefore, since *Bifidobacterium* and milk are included in the composition, the disclosed composition would necessarily comprise arginine, spermine, and spermidine.

As outlined previously, the instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with at least one microorganism to an infant, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

Haschke *et al.* disclose a method of administering, to infants, a composition comprising a probiotic organism, non-digestible oligosaccharides, and specific fats (see page 6, lines 10-20; page 5, lines 1-5; page 4, lines 15-25). Bacteria such as *Bifidobacterium* contain numerous proteins, some of which include arginine. Moreover, Haschke includes milk in their composition. It is known in the art spermine and spermidine are constituents of milk (see for example, Motyl *et al.*, Comp. Biochem. Physiol., 111B:427-433, 1995). Therefore, since *Bifidobacterium* and milk are included in the composition, the disclosed composition would necessarily comprise arginine, spermine, and spermidine.

Although Haschke *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201

USPQ 658 (CCPA 1979). Therefore, the disclosure of Haschke *et al.* anticipates the instant claims.

The rejection of claims 11 and 17-18 under 35 U.S.C. 102(b) as being anticipated by Giffard *et al.* (WO 03/041512 A1, 5/2003), is maintained for the reasons set forth in the previous office action.

**Applicant argues:**

1. That applicant has surprisingly found that gut barrier function or gastrointestinal health may be improved by providing specific bioactive ingredients combined with microorganisms that are able to deliver at least one of the ingredients all along the intestine. Applicant asserts that the microorganisms of the claims differ in their ability to survive in the different parts of the gastro-intestinal tract and can be incorporated into a cocktail with bioactive ingredients that reinforce their effects by stimulating the maturation of barrier mechanisms. Applicant asserts that the microorganisms of the present invention are designed to release the specific bioactive ingredients at a certain location of the gut depending on the sort of pretreatment undergone by the microorganism and that the polyamines and/or polyamine precursors of amended claim 11 also provide the advantages of substances that have the potential to favor intestinal cell differentiation.

2. That Giffard *et al.* fail to disclose or suggest administering a composition comprising at least one substance selected from the group consisting of fats, non-digestible oligosaccharides, or combinations thereof and at least one microorganism, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine. Applicant argues that, instead, Giffard is entirely directed toward a foodstuff which comprises colostrum as a primary ingredient. Applicant asserts that Giffard does not suggest the use of a polyamide or polyamide precursor, let alone those recited in claim 11.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, the claims lack any mention of particular organisms that are designed to release specific bioactive ingredients in specific locations of the gut. What is required by the claims is administration of a combination of fats or non-digestible oligosaccharides and at least one microorganism, wherein the combination comprises

spermidine, spermine, putrescine, cadaverine, ornithine, or arginine. This is exactly what is taught by Giffard *et al.*

Regarding argument 2, the “foodstuff” Giffard discloses is not composed only of colostrum. Giffard explicitly discloses the inclusion of probiotic microorganisms and colostrum (see pages 3, 4, 5, and 6, for example). Bacteria such as *Bifidobacterium* contain numerous proteins, some of which include arginine. Moreover, Giffard includes colostrum in their composition. It is known in the art spermine and spermidine are constituents of colostrum (see for example, Motyl *et al.*, Comp. Biochem. Physiol., 111B:427-433, 1995). Therefore, since *Bifidobacterium* and colostrum are included in the composition, the disclosed composition would necessarily comprise arginine, spermine, and spermidine.

As outlined previously, the instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with at least one microorganism to an infant, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

Giffard *et al.* disclose a method of administering, to infants, a composition comprising a probiotic organism, prebiotic (non-digestible oligosaccharides), and specific fats (see page 19, lines 1-20; page 18, lines 5-10; page 8, lines 15-25; page 7, lines 25-30). Bacteria such as *Bifidobacterium* contain numerous proteins, some of which include arginine. Moreover, Giffard *et al.* include colostrum in their composition. It is known in the art spermine and spermidine are constituents of colostrum (see for example, Motyl *et al.*, Comp. Biochem. Physiol., 111B:427-433, 1995). Therefore, since *Bifidobacterium* and colostrum are included in the composition, the disclosed composition would necessarily comprise arginine, spermine, and spermidine.

Although Giffard *et al.* are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508

(CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the disclosure of Giffard *et al.* anticipates the instant claims.

### ***New Claim Rejections***

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 11 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 4-7 of copending Application No. 12/593,462. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with at least one microorganism to an infant, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

The claims of the copending application are drawn to methods of administering, to an infant, a composition comprising N-acetylated oligosaccharides and *Bifidobacterium lactis*. The N-acetylated oligosaccharides listed in the claims are non-digestible. Bacteria such as *Bifidobacterium* contain numerous proteins, some of which include arginine. Therefore, since *Bifidobacterium* is included in the composition, the disclosed composition would necessarily comprise arginine.

Although the copending claims are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the copending claims anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-9 of copending Application No. 12/593,457. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with at least one microorganism to an infant, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

The claims of the copending application are drawn to methods of administering, to an infant, a composition comprising N-acetylated oligosaccharides and *Bifidobacterium lactis*. The N-acetylated oligosaccharides listed in the claims are non-digestible. Bacteria such as *Bifidobacterium* contain numerous proteins, some of which include arginine. Therefore, since *Bifidobacterium* is included in the composition, the disclosed composition would necessarily comprise arginine.

Although the copending claims are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the copending claims anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6-9 of copending Application No. 12/532,056. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with at least one microorganism to an infant, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

The claims of the copending application are drawn to methods of administering, to an infant, a composition comprising N-acetylated oligosaccharides and *Bifidobacterium*. The N-acetylated oligosaccharides listed in the claims are non-digestible. Bacteria such as *Bifidobacterium* contain numerous proteins, some of which include arginine. Therefore, since *Bifidobacterium* is included in the composition, the disclosed composition would necessarily comprise arginine.

Although the copending claims are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the copending claims anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 11 and 17-18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 12/532,021. Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons.

The instant claims are drawn to a method for inducing a pattern of gut barrier maturation similar to that observed with breast-feeding comprising administering a combination of specific fats and/or non-digestible oligosaccharides, associated with at least one microorganism to an infant, wherein the combination comprises spermidine, spermine, putrescine, cadaverine, ornithine, or arginine (claim 11); further comprising ensuring an optimal barrier function in infants (claim 17); and further reducing the risk of developing allergy and infection (claim 18).

The claims of the pending application are drawn to methods of administering, to an infant, a composition comprising N-acetylated oligosaccharides and *Lactobacillus*. The N-acetylated oligosaccharides listed in the claims are non-digestible. Bacteria such as *Lactobacillus* contain numerous proteins, some of which include arginine. Therefore, since *Lactobacillus* is included in the composition, the disclosed composition would necessarily comprise arginine.

Although the pending claims are silent with regard to inducing a pattern of gut barrier maturation, they disclose the administration of the same product to the same population as is instantly claimed and it does not appear that it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See Bristol-Myers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001). It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable. In re Woodruff, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). The mechanism of action does not have a bearing on the patentability of the invention if the invention was already known or obvious. Mere recognition of latent properties in the prior art does not render nonobvious an otherwise known invention. In re Wiseman, 201 USPQ 658 (CCPA 1979). Therefore, the pending claims anticipate the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 17 is rendered vague and indefinite by the phrase “further comprising the step of ensuring optimal barrier function in infants by administering the combination of at least one substance.” It is not clear how the step of claim 17 is intended to fit into the method of the parent claim. The parent claim does not refer to administration of a “combination of at least one substance.” The phrase “at least one substance” refers to at least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof. Therefore, there is no “combination of at least one substance.” The “combination” in the parent claim is a combination of the at least one substance selected from fats, non-digestible oligosaccharides and combinations thereof with at least one microorganism. Therefore, strictly speaking, the term “combination of at least one substance” lacks antecedent basis. In addition, if one were to consider the term to be a reference to the composition in the parent claim, then administration of the “combination of at least one substance” is already part of the parent claim and thus there is no further step. It is not clear how claim 17 can “further comprise” a step that is already a part of the parent claim.

Claim 18 is rendered vague and indefinite by the phrase “further comprising the step of reducing the risk of developing allergy and infection by administering the combination of at least one substance.” It is not clear how the step of claim 18 is intended to fit into the method of the parent claim. The parent claim does not refer to administration of a “combination of at least one substance.” The phrase “at least one substance” refers to at least one substance selected from the group consisting of fats, non-digestible oligosaccharides and combinations thereof. Therefore, there is no “combination of at least one substance.” The “combination” in the parent claim is a combination of the at least one substance selected from fats, non-digestible oligosaccharides and combinations thereof with at least one microorganism. Therefore, strictly speaking, the term “combination of at least one substance” lacks antecedent basis. In addition, if one were to consider the term to be a reference to the composition in the parent claim, then administration of the “combination of at least one substance” is already part of the parent claim and thus there is

no further step. It is not clear how claim 18 can "further comprise" a step that is already a part of the parent claim.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571) 272-1181. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Patricia Duffy can be reached on (571) 272-0855. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/  
Examiner, Art Unit 1645